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Signed

Dated 21 October 2004

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23MAR04 E883081-1 002058
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Request for grant of a patent

(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)

1. Your reference

6/LC/P13483.GB

2. Patent application number
(The Patent Office will fill in this part)

0406458.0

23 MAR 2004

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

Barry Peter Liversidge,
The Wick,
Wick Road,
Langham,
Colchester,
Essex CO4 5PE

Patents ADP number *(if you know it)*

If the applicant is a corporate body, give the country/state of its incorporation

4. Title of the invention

SAFETY MEDICAL NEEDLE ASSEMBLIES

5. Name of your agent *(if you have one)*

Sanderson & Co.

"Address for service" in the United Kingdom to which all correspondence should be sent *(including postcode)*

34 East Stockwell Street
Colchester
Essex
CO1 1ST

Patents ADP number *(if you know it)*

1446001

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number

Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*
GB	03 23653.6	9/10/03

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application	Date of filing *(day / month / year)*

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? *(Answer 'Yes' if:*

a) any applicant named in part 3 is not an inventor, or
b) there is an inventor who is not named as an applicant, or
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See note (d))

No

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9. Enter the number of sheets for any of the following items you are filing with this form. Do not count copies of the same document

Continuation sheets of this form	
Description	12
Claim(s)	2
Abstract	-
Drawing(s)	9 +9 fm.

10. If you are also filing any of the following, state how many against each item.

Priority documents	
Translations of priority documents	
Statement of inventorship and right to grant of a patent *(Patents Form 7/77)*	
Request for preliminary examination and search *(Patents Form 9/77)*	
Request for substantive examination *(Patents Form 10/77)*	
Any other documents *(Please specify)*	

11. I/We request the grant of a patent on the basis of this application

Sanderson & Co.
Agents for the applicant

Signature

Date
22nd March 2004

12. Name and daytime telephone number of person to contact in the United Kingdom

Francis C. Gillam – 01206 571187

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SAFETY MEDICAL NEEDLE ASSEMBLIES

This invention concerns further embodiments of the invention described and claimed in my earlier British Application No. 03 23653.6, entitled *Latching Blocking Mechanisms and Safety Medical Needle Assemblies* ("said application") and the priority of said application is claimed hereby. In particular, this invention relates to another arrangement of the concept described and claimed in said application.

In the specification of said application, there are described various embodiments of safety medical needle assemblies intended for use with conventional syringes carrying medical needles through which medicaments may be injected into a human or animal body or through which fluids may be withdrawn from a body. Consequent upon further development of the invention of said application, with a particular view to providing a passive safety assembly suitable for use with a conventional pre-filled syringe containing a relatively small volume (and typically a few ml) of medicament, the embodiments of this application have been produced.

Pre-filled syringes are used on a very wide scale, and increasingly so. Usually, the body of such a syringe is of glass having regard to the inert nature of that material, to which a relatively fine and usually quite short needle is permanently secured to a hub formed integrally with the body, during the manufacture of the syringe. Following filling of the syringe with the required volume of liquid medicament, a plunger having a piston is fitted into the body of the syringe and a needle sheath is fitted over the needle. The pre-filled syringe is then sealed in a sterile package until required for use.

Generally, such pre-filled syringes are significantly smaller both in diameter and length than the majority of conventional syringes which are to be filled with a medicament at the time of use, by the person who is to administer the medicament. As such, it is more difficult to furnish a pre-filled syringe of this kind with a passive protection device as described in said application. It is an aim of the present invention to provide a passive protection device suitable for use with a pre-filled syringe.

In said application, I have claimed a safety medical needle assembly, comprising:

– a tubular component including an internal elongate guide;

– an abutment surface formed on the tubular component;

– a movable component disposed within the tubular component and arranged for axial sliding movement with respect thereto between initial and forward positions, the movable component being adapted to receive the hub of a medical needle so that the needle projects forwardly within but is protected by the tubular component when the movable component is in its initial position;

– a control member arranged for axial movement with the movable component but rotatable with respect to the movable component, the control member initially being disposed at a first position relative to the movable component;

– control means arranged to urge the control member towards a second position angularly displaced from the first position, which control means becomes active only after the control member has turned through a predetermined angle towards the second position; and

– a camming part on the tubular component co-operable with a moving camming part on the control member and arranged to turn the control member through said predetermined angle from its first position on axial movement of the movable component towards its forward position to cause the needle to project from the tubular component;

– whereby the movement of the movable component towards its forward position to cause the needle to project from the tubular component also causes the control member to turn through said predetermined angle whereafter the return of the movable component towards its initial position allows the control member to move behind the abutment surface under the action of the control means, thereafter to block further axial movement of the movable component towards its forward position.

In the above definition of the invention of said application, references are made to the "forward" position of various components, and within the context of that specification, the term "forward" is used to refer to the end of a syringe which carries a needle, and "forwardly" to the direction of projection of a needle from the syringe. However, as noted in the specification of said application, the terms "forward", "forwardly", "rearward" and "rearwardly" are all relative and in effect merely refer to opposite ends of the assembly and the directions towards those opposite ends, respectively. For instance, it is a moot point when a needle is to project from the safety needle assembly of said application in an unprotected manner with the tubular component withdrawn from its protecting position whether the tubular component remains stationary and the movable

component moves forwardly to expose the needle, or whether the tubular component moves rearwardly with respect to the movable component.

To obviate this difficulty over the directions of relative movement of the various parts of the safety needle assembly of the invention of said application, the invention thereof as set out above may be redefined as follows.

A safety needle assembly comprising:

– a tubular component including an internal elongate guide;

– an abutment surface formed on the tubular component;

– a movable component disposed within the tubular component and arranged for axial sliding movement with respect thereto between initial and shifted positions, the movable component being adapted to receive the hub of a medical needle so that the needle projects within but is protected by the movable component when in its initial position;

– a control member arranged for axial movement with the movable component but rotatable with respect to the movable component, the control member initially being disposed at a first position relative to the movable component;

– control means arranged to urge the control member towards a second position angularly displaced from the first position, which control means becomes active only after the control member has turned through a predetermined angle towards the second position; and

– a camming part on the tubular component co-operable with a moving camming part on the control member and arranged to turn the control member through said predetermined angle from its first position on axial movement of

the movable component towards its shifted position to cause the needle to project from the movable component;

– whereby the movement of the movable component towards its shifted position to cause the needle to project therefrom also causes the control member to turn through said predetermined angle whereafter the return of the movable component towards its initial position allows the control member to move behind the abutment surface under the action of the control means, thereafter to block further axial movement of the movable component towards its forward position.

It is to be noted that in this slightly revised definition of the invention, the terms "forward", "forwardly", "rearward" and "rearwardly" are no longer used; rather, the movement of the movable component is defined as between *initial* and *shifted* positions. Consequent upon this, the definitions of the other components and their directions of movement have also been revised. Despite this, it will be appreciated that the inventive concept of this revised definition is identical to that of said application.

By way of example only, two specific embodiments of passive safety devices for use with pre-filled syringes and which are arranged in accordance with the invention of said application will now be described in detail, reference being made to the accompanying drawings in which:-

Figures 9A to 9H are isometric illustrations of a first embodiment of passive safety needle assembly for use with a pre-filled syringe, with various parts cut-away for clarity, wherein Figures 9A to 9H show the successive steps

of the operation of the assembly from an initial setting to a latched and blocked setting; and

Figures 10A to 10J are isometric illustrations of a second embodiment of safety needle assembly for use with a pre-filled syringe, being a modification of the first embodiment of Figures 9A to 9H and again showing the successive steps of the operation of the assembly.

It is to be noted that the capital letter 'I' has not been used as a suffix in designating the figure numbers of the second embodiment, in order to avoid confusion with the numeral 1.

As in the spec of said application, in the embodiments of Figures 9 and 10, the terms "forward" and "forwardly" refer to the direction of arrow A marked on those figures and arrow B indicates the rearward direction.

Referring now to Figure 9A to 9H, there is shown a pre-filled syringe having a glass body 115 defining a cylindrical chamber for a liquid medicament to be dispensed, the syringe having a plunger 116 fitted with a piston (not shown), for expelling the medicament pre-filled into the body 115 at the time of manufacture. The body has a hub at its forward end to which a needle 117 (Figures 9E and 9F) is permanently secured, which needle is protected by a sheath (also not shown) at the time of manufacture but which must be removed before fitting the syringe to the safety assembly of this embodiment.

The passive safety assembly comprises an outer sleeve 118 within which the body 115 is received from the rearward open end 119 thereof, that open end of the sleeve being internally profiled to engage with a flange 120

formed at the rearward end of the syringe body. In this way, once the syringe has been pushed fully into the sleeve, it is retained therein.

A movable component 121 is slidably received within the sleeve and also is slidable over the outer surface of the body 115 of the syringe. In its initial position shown in Figures 9A to 9C, the component 121 projects to its fullest extent from the outer sleeve 118 and so wholly encloses the needle 117. At its rearward end, the movable component 121 has three control parts 122, each having a first control surface 123 and a second control surface 124, which control parts and first and second control surfaces correspond to the control parts 54 and first and second control surfaces 55 and 56 of the embodiment described with reference to Figure 5 of said application.

Also slidably mounted within the outer sleeve 118 is a control member 126, biased to the forward position shown in Figures 9B and 9C by a helical compression spring 127 acting between the control member and an annular abutment 128 formed within the rearward open end 119 of the body 115. By virtue of the control member 126 bearing on the movable component 121, that component 121 is also urged to its initial position, projecting to the greatest extent from the outer sleeve 118, as shown in Figures 9A to 9C.

Three parallel guides 129 are formed internally of the outer sleeve 118 at equi-spaced intervals and extend for the greater part of the length of the outer sleeve. The control member 126 is of a similar form to control member 58 of Figure 5 of said application and has three bars 130 each having a rounded forward end 131 for cooperating with the first and second control surfaces 123 and 124. Associated with each bar 130 is a lateral projection 132

(corresponding to lateral projection 23 of Figure 5) for cooperation with a respective guide 129 and a blocking member 133 (corresponding to blocking member 26 of Figure 5) also for cooperation with a respective guide 129.

As will be appreciated, the arrangement of the control parts 122, the control member 126 and the guides 129 all have the same functionality as the corresponding parts 54, control member 58 and guides 51 of the embodiment of Figure 5. As such, the operation of the mechanism will be described only briefly, here.

The initial setting of the assembly is shown in Figures 9A, 9B and 9C, Figure 9C showing the components in the same relative positions as Figure 9B but with more of the outer sleeve 118 cut away and also with the assembly turned through approximately 60° for the sake of clarity. The movable component 121 projects to the greatest extent from the outer sleeve 118, and is urged to that position by the spring 127 acting through the control member 126.

Though there are three identical mechanisms spaced around the assembly, the action of only one of those will be described in the following. The rounded forward end 131 of the bar 130 bears on the first control surface 123 of the movable component 121 but the control member cannot rotate in a counter-clockwise direction when viewed from the open forward end 135 of the movable component 121 furthest from the syringe, by virtue of the interaction of the other end of the bar 130 with an adjacent guide 129 (Figure 9C). When an injection is to be performed, the open forward end 135 of the movable component is engaged with the injection site and on applying pressure by holding the outer sleeve 118 and moving it towards the injection site, the

movable component 121 starts to move towards its withdrawn position within the outer sleeve 118, in the rearward direction of arrow B.

Almost immediately, the forward end of guide 129 engages the lateral projection 132 and, by virtue of the cam face 136 of that projection, the control member is turned in a clockwise direction, when viewed as aforesaid (Figure 9D). This causes the rounded forward end 131 of bar 130 to ride over apex 137 between the first and second control surfaces 123,124 so that the control member 122 is now urged in a clockwise sense by the interaction of the bar 130 with the second control surface 124 (Figure 9E). The turning of the control member in that sense is limited by the blocking member 133 engaging the next adjacent guide 129. As best seen in Figures 9D and 9E, a slot 138 is formed in the forward end of the movable component 121, to accommodate the guide 129 and prevent relative rotational movement between the outer sleeve 118 and the movable component 121.

When the movable component 121 has moved fully rearwardly to its withdrawn position (Figure 9E) and the needle 117 projects to the greatest extent, the injection of the medicament is performed by depressing the plunger 116 (Figure 9F), whereafter the entire assembly is moved away from the injection site. This allows the movable component 121 to return to its initial position under the action of spring 127 (Figure 9G). Once the blocking member 133 comes free of the guide 129, the control member 126 is allowed to turn further in a clockwise sense as the rounded forward end 131 of bar 130 is urged to run down the second control surface 124, so bringing the blocking member 133 into alignment with the guide 129 (Figure 9H). When in this

position, the blocking member 123 will now prevent withdrawal movement of the movable component 121 in the direction of arrow B, thereby preventing the needle 117 being exposed for a second time.

Figures 10A to 10J illustrate a similar arrangement to that described above, but differing in certain respects which will be explained below. However, the basic operating principle of the assembly is essentially the same and so components having the same function as those of the previous embodiment are given the same reference characters and will not therefore be described in detail once more.

With the embodiment of Figure 9, the mechanism is set ready to be triggered as soon as the movable component 121 starts its withdrawal movement in the direction of arrow B. With the embodiment of Figure 10, the mechanism is initially unset and becomes set for triggering only on removing a cap 140 fitted into the forward end 135 of the movable component 121. This is advantageous when it is necessary to adjust the dose to be dispensed by the pre-filled syringe, before performing an injection.

The cap 140 is arranged to engage the hub end of the syringe within the mechanism, so as to hold the movable component 121 in the position shown in Figures 10A and 10B, and so partially in a withdrawn position. However, the needle remains protected by virtue of the cap 140. By manufacturing both the outer sleeve 118 and the movable component 121 from transparent materials, the syringe will be visible within those components and so the quantity of medicament within the syringe may also be seen. When the assembly is in the initial position of Figures 10A and 10B, the plunger may be partially depressed

to expel the excess medicament from the syringe until the required quantity remains therewithin, as determined by viewing the position of the piston within the syringe body.

The cap 140 is then pulled in the direction of arrow A to come free of the syringe hub and to draw the movable component 121 in the same direction, so as further to project from the outer sleeve 118 (Figure 10C). During this, the bar 141 of the movable component 121 slides down the adjacent guide 129 and eventually comes free of that guide, as the cap 140 comes away from the movable component 121. This allows the mechanism to be set, with a cam surface 143 formed on the rearward end of bar 141 presented to the forward end of a guide 129 (Figure 10D). An injection may then be performed as described above with reference to Figure 9, but during the initial stage of the movable component moving rearwardly in the direction of arrow B, the cam surface 143 on bar 141 turns the control member 142 in the counter-clockwise direction, to cause the rounded forward end of the bar to ride over the apex 137 between the first and second control surfaces 123,124 (Figure 10E), as has been described above.

Continued withdrawal movement of the movable component exposes the needle 117 (Figure 10F) but further rotation of the control member 142 is prevented by the blocking member 133 thereof engaging an adjacent guide 129. When the movable component 121 has withdrawn fully, so exposing the needle 117, an injection is performed by pressing the plunger 116 (Figure 10G) and then the entire assembly is moved away from the injection site, so allowing the movable component 121 to move fully forwardly in the direction of arrow A

(Figure 10H). When the blocking member 133 comes free of guide 129, the control member is urged to turn further in a counter-clockwise sense by the rounded forward end of the bar 141 bearing on second control surface 124, so bringing the blocking member into alignment with the guide 129 (Figure 10J). This blocks withdrawal movement of the movable component 121 for a second time, in the direction of arrow B.

CLAIMS

1. A safety needle assembly comprising:

– a tubular component including an internal elongate guide;

– an abutment surface formed on the tubular component;

– a movable component disposed within the tubular component and arranged for axial sliding movement with respect thereto between initial and shifted positions, the movable component being adapted to receive the hub of a medical needle so that the needle projects within but is protected by the movable component when in its initial position;

– a control member arranged for axial movement with the movable component but rotatable with respect to the movable component, the control member initially being disposed at a first position relative to the movable component;

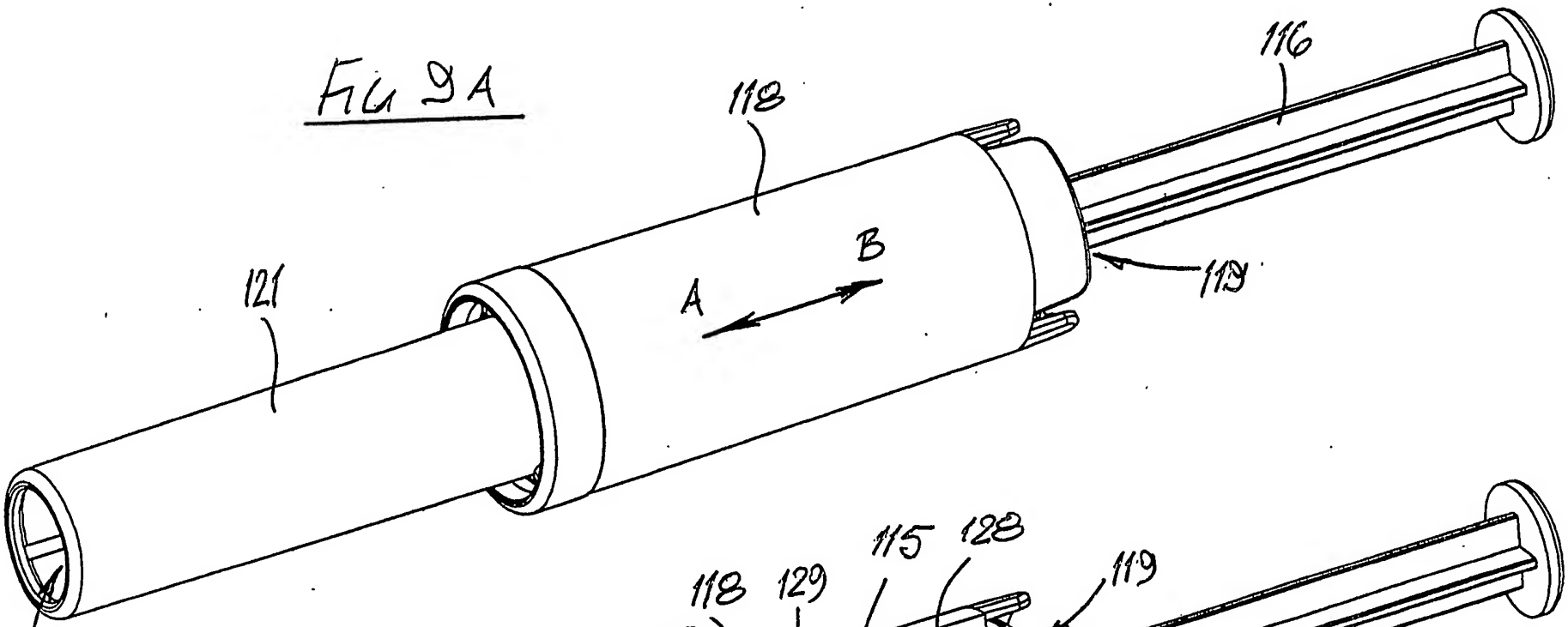
– control means arranged to urge the control member towards a second position angularly displaced from the first position, which control means becomes active only after the control member has turned through a predetermined angle towards the second position; and

– a camming part on the tubular component co-operable with a moving camming part on the control member and arranged to turn the control member through said predetermined angle from its first position on axial movement of the movable component towards its shifted position to cause the needle to project from the movable component;

– whereby the movement of the movable component towards its shifted position to cause the needle to project therefrom also causes the control

member to turn through said predetermined angle whereafter the return of the movable component towards its initial position allows the control member to move behind the abutment surface under the action of the control means, thereafter to block further axial movement of the movable component towards its forward position.

FIG 9A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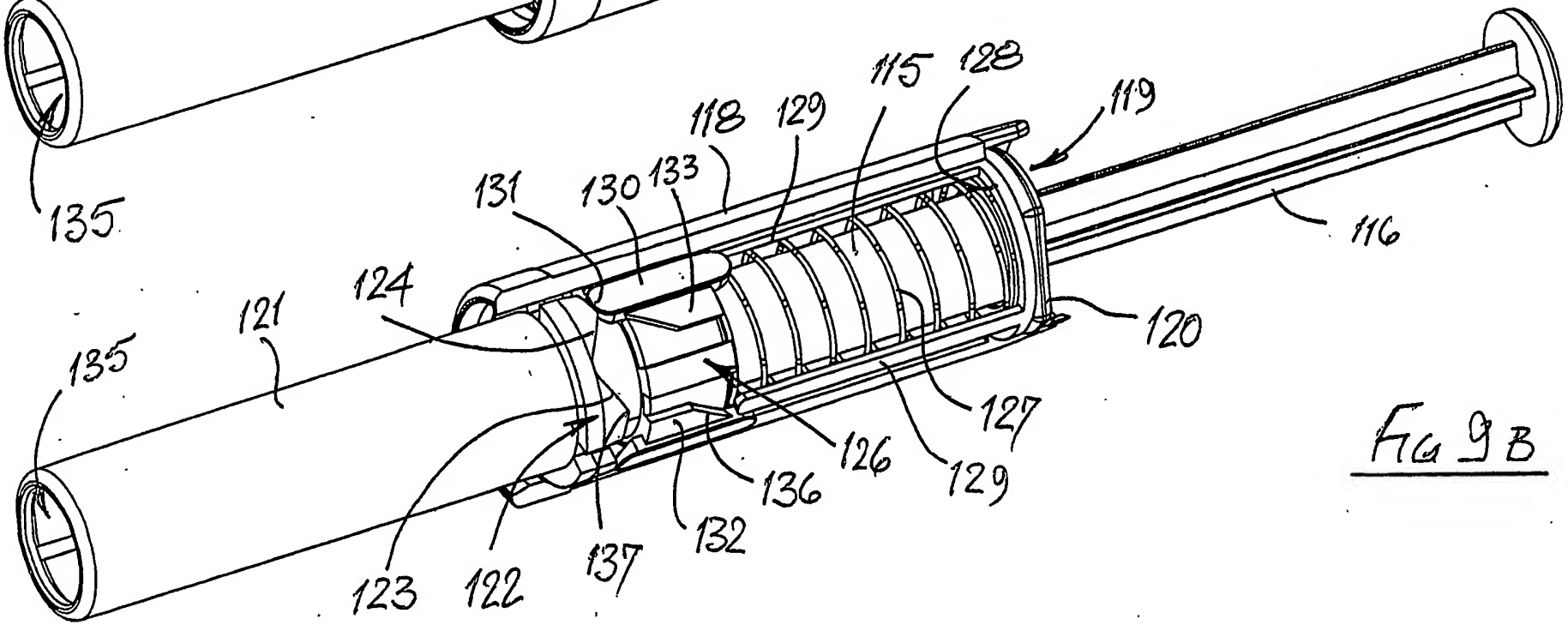
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FIG 9B

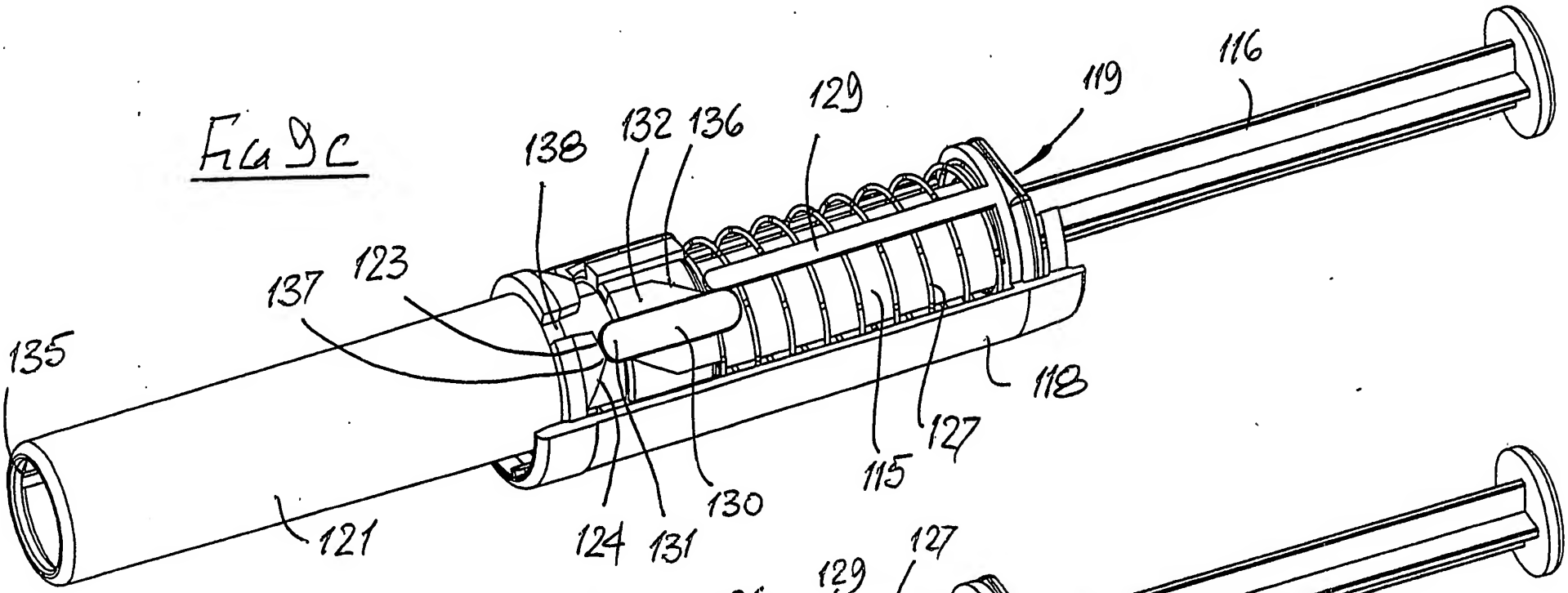
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FIG 9C

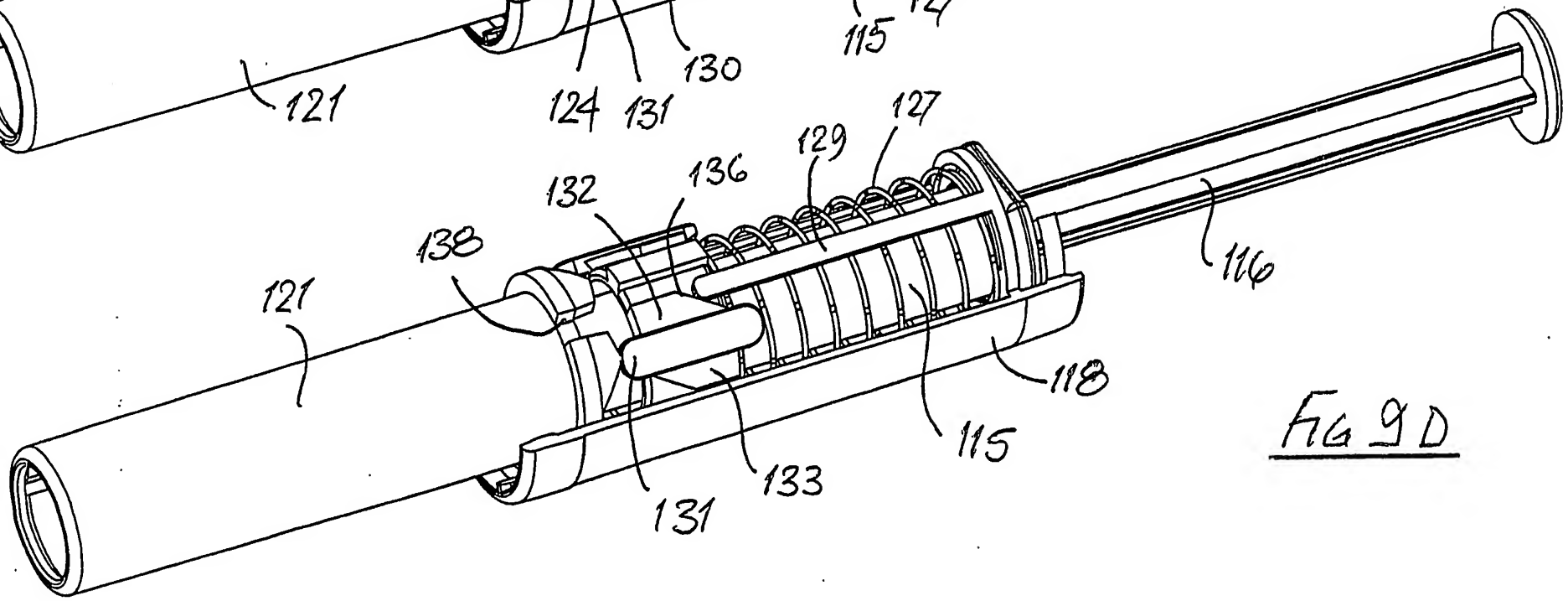
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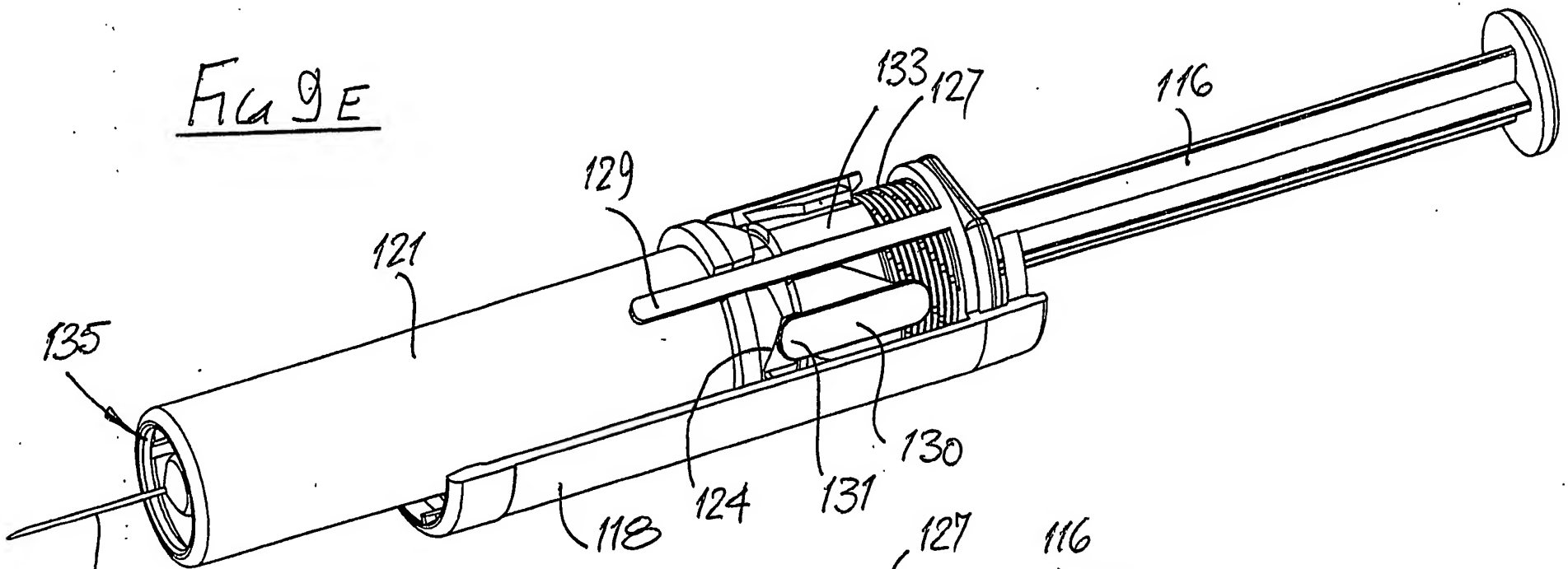
FIG 9D

FIG 9E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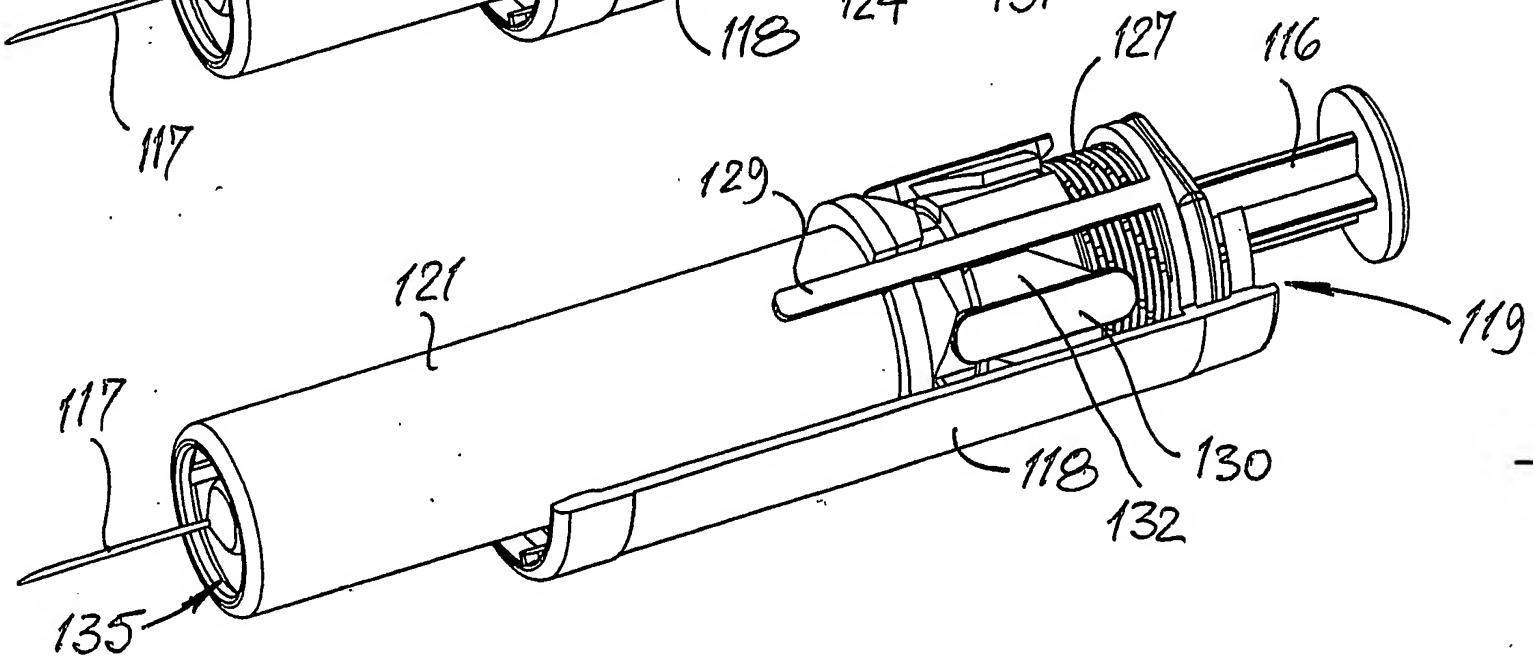
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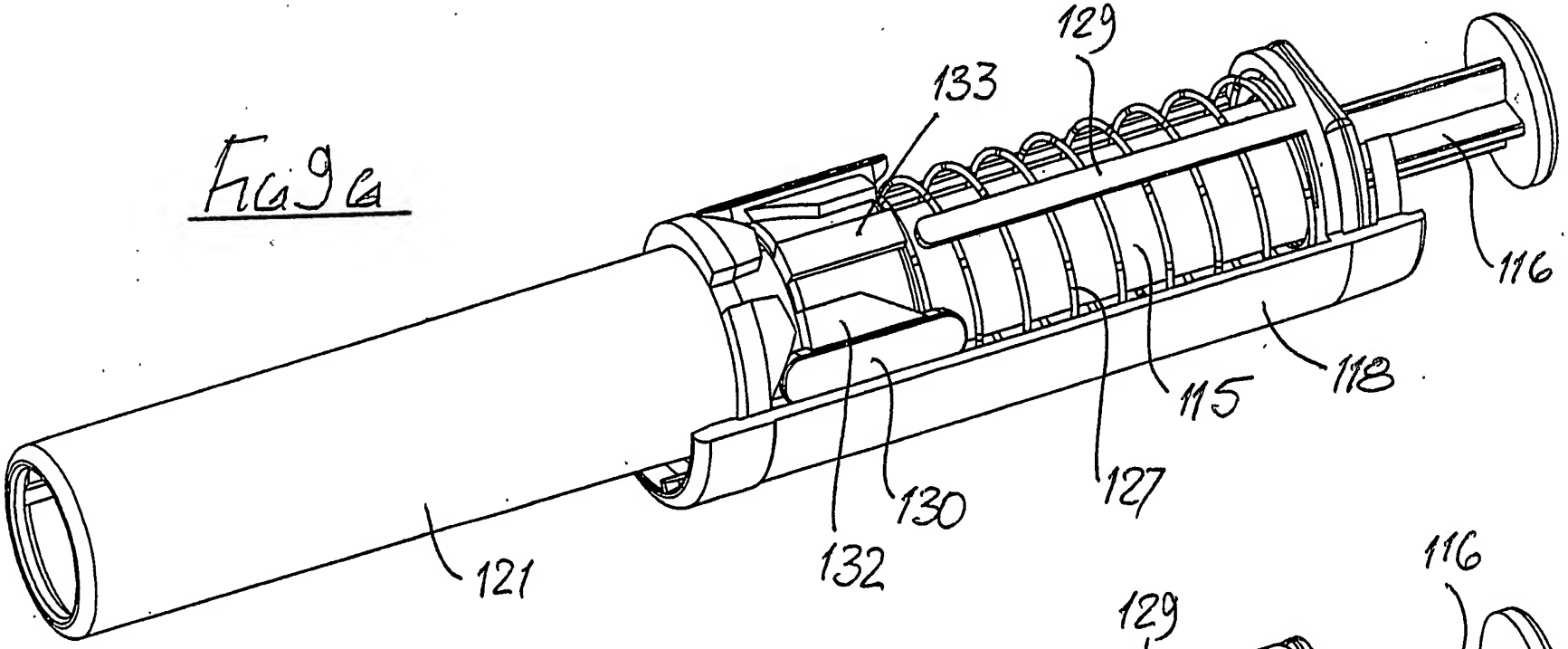
FIG 9F

Fig 9G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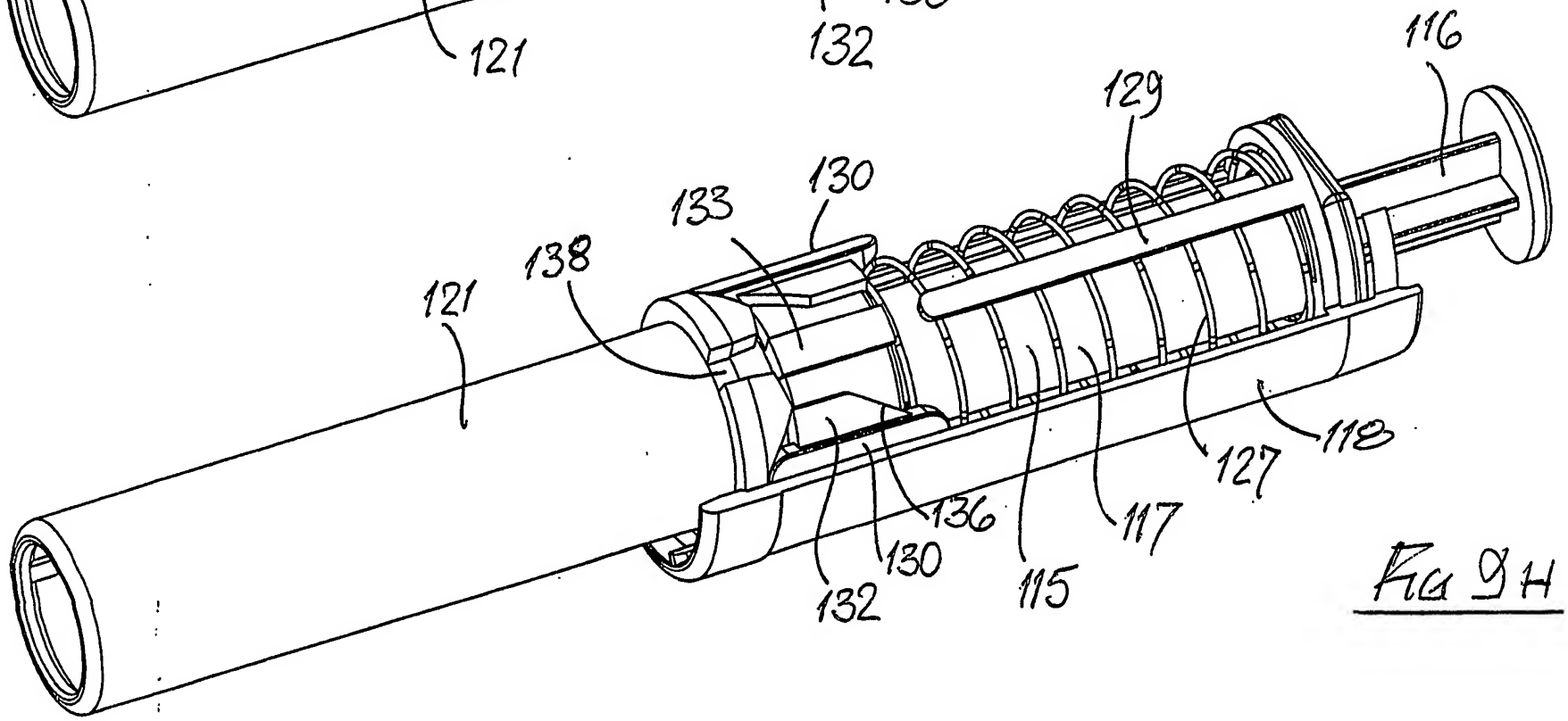
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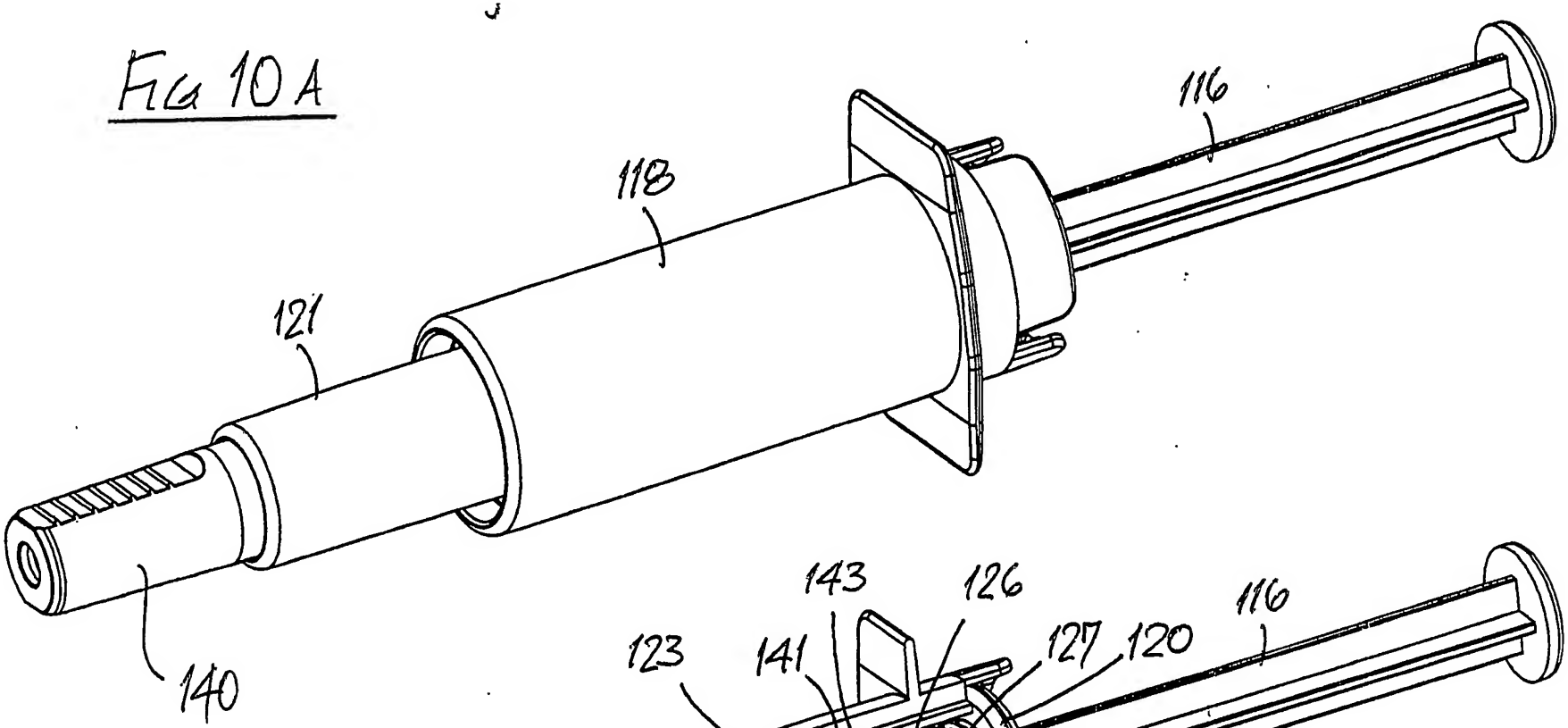
Fig 9H

FIG 10A



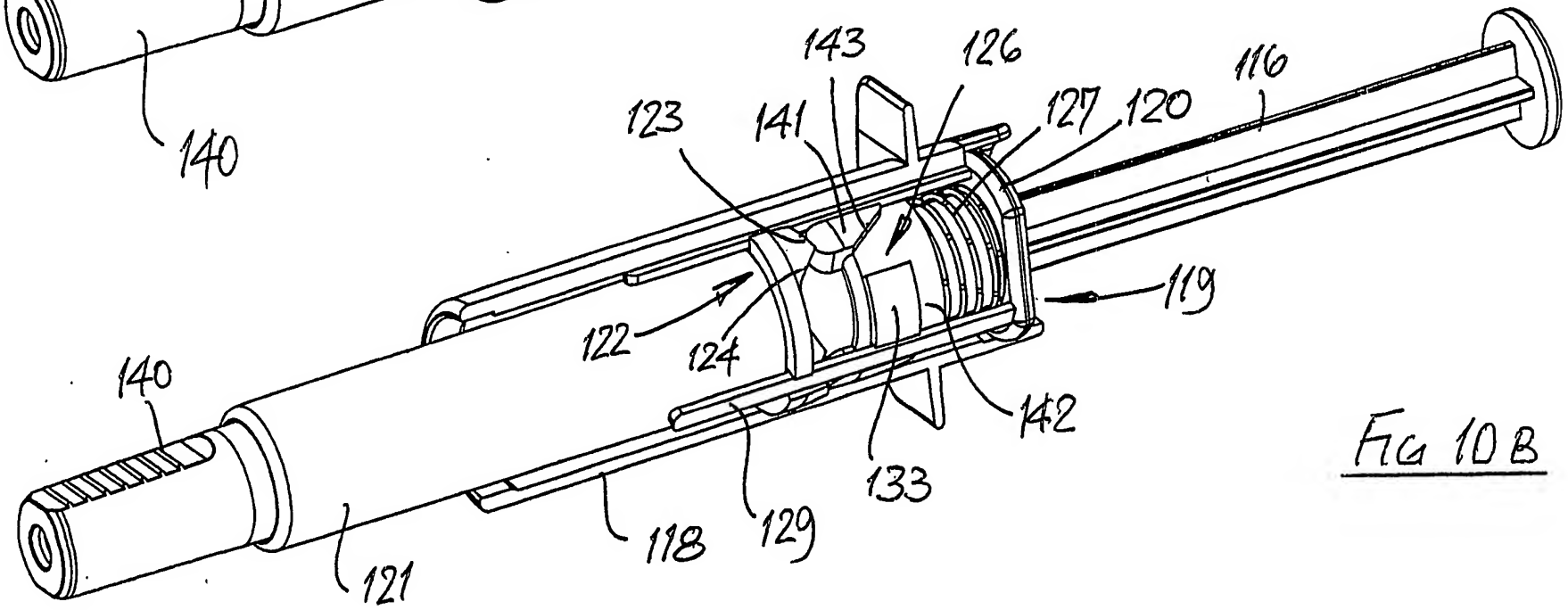
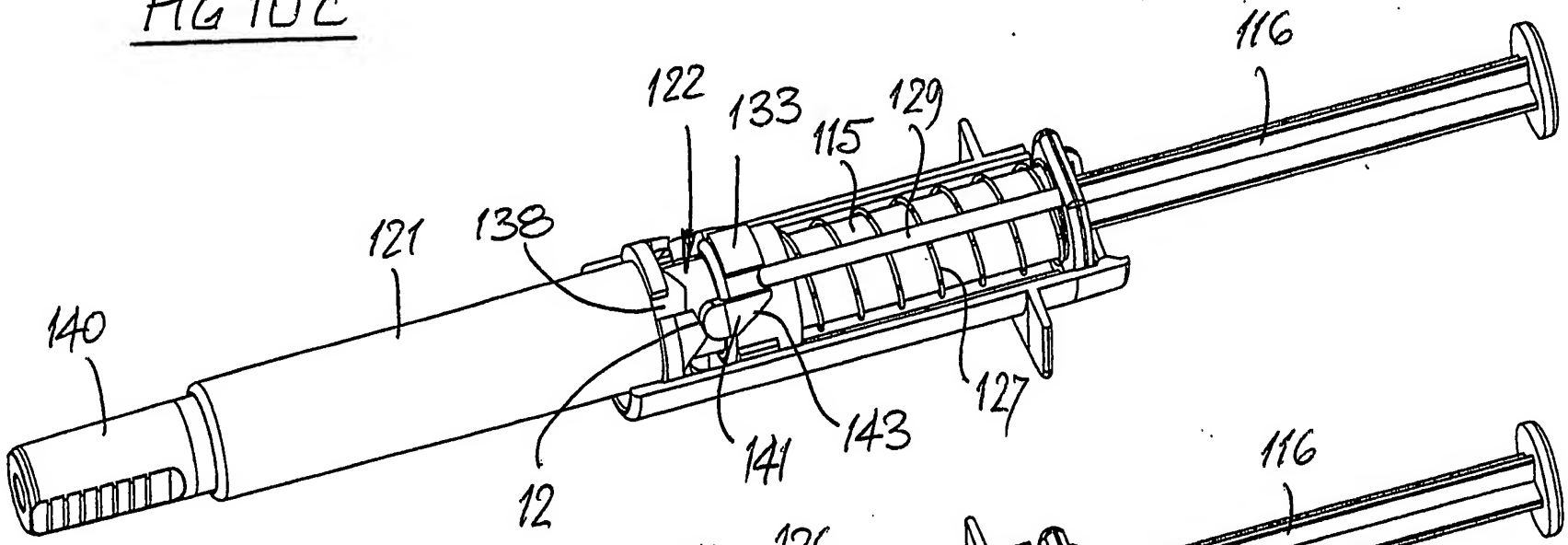


FIG 10B

FIG 10C



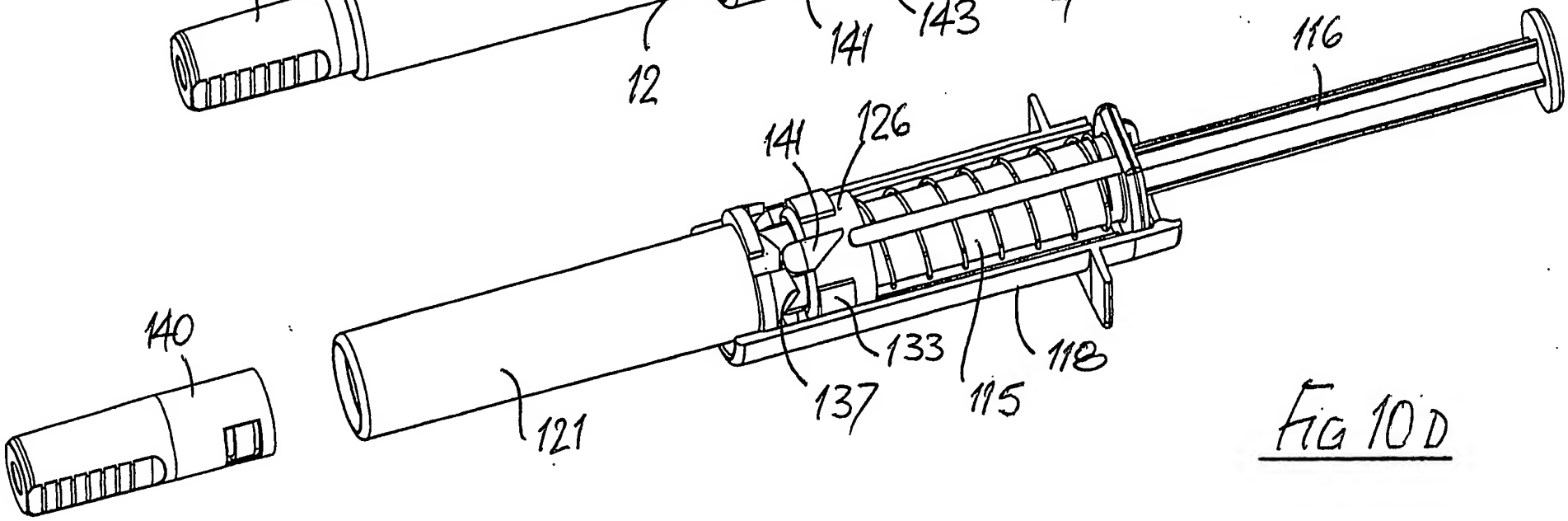
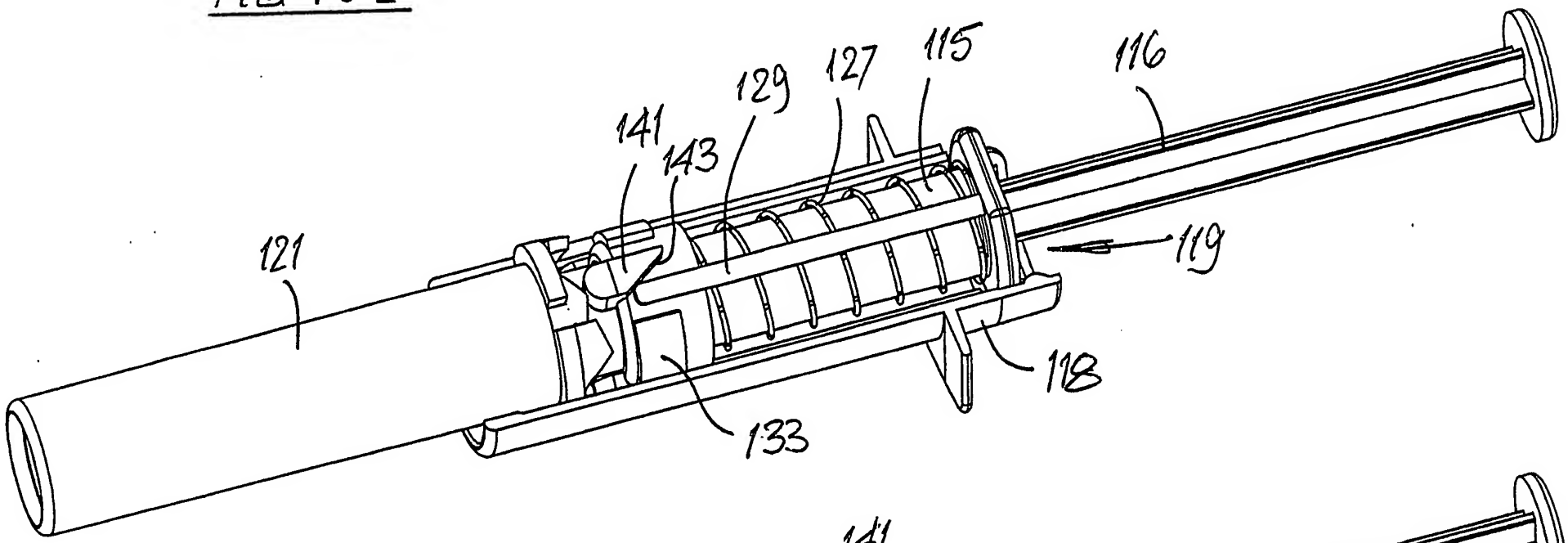


FIG 10D

FIG 10 E



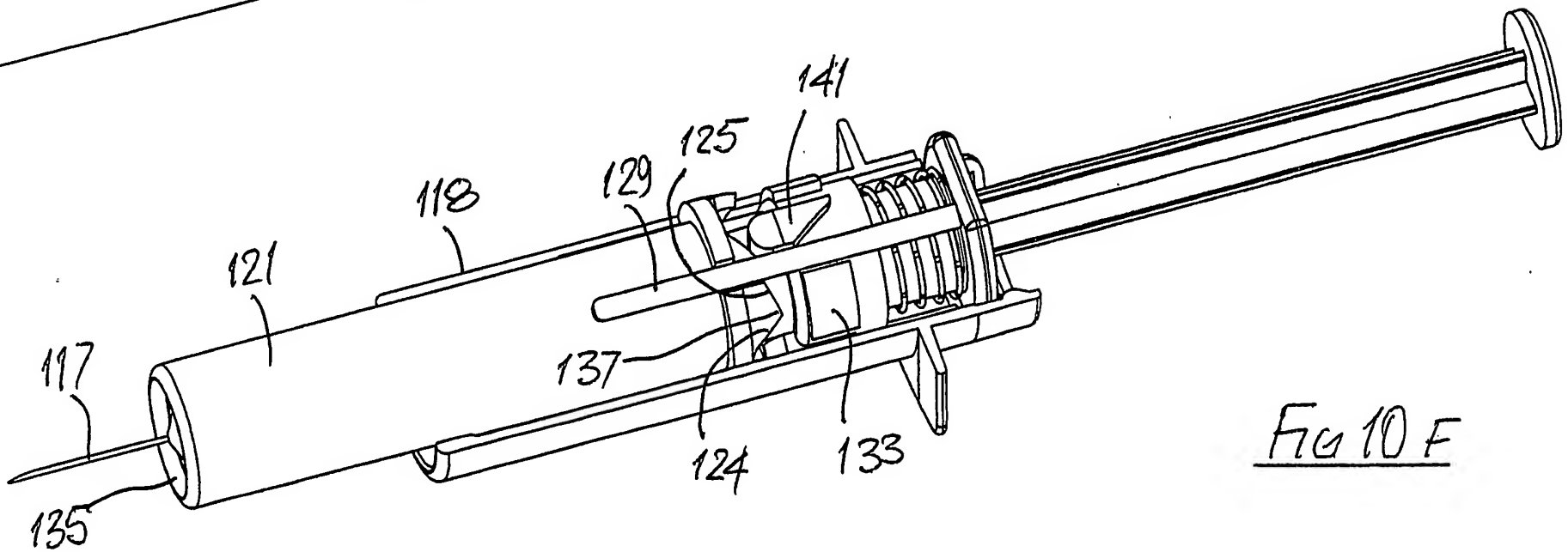
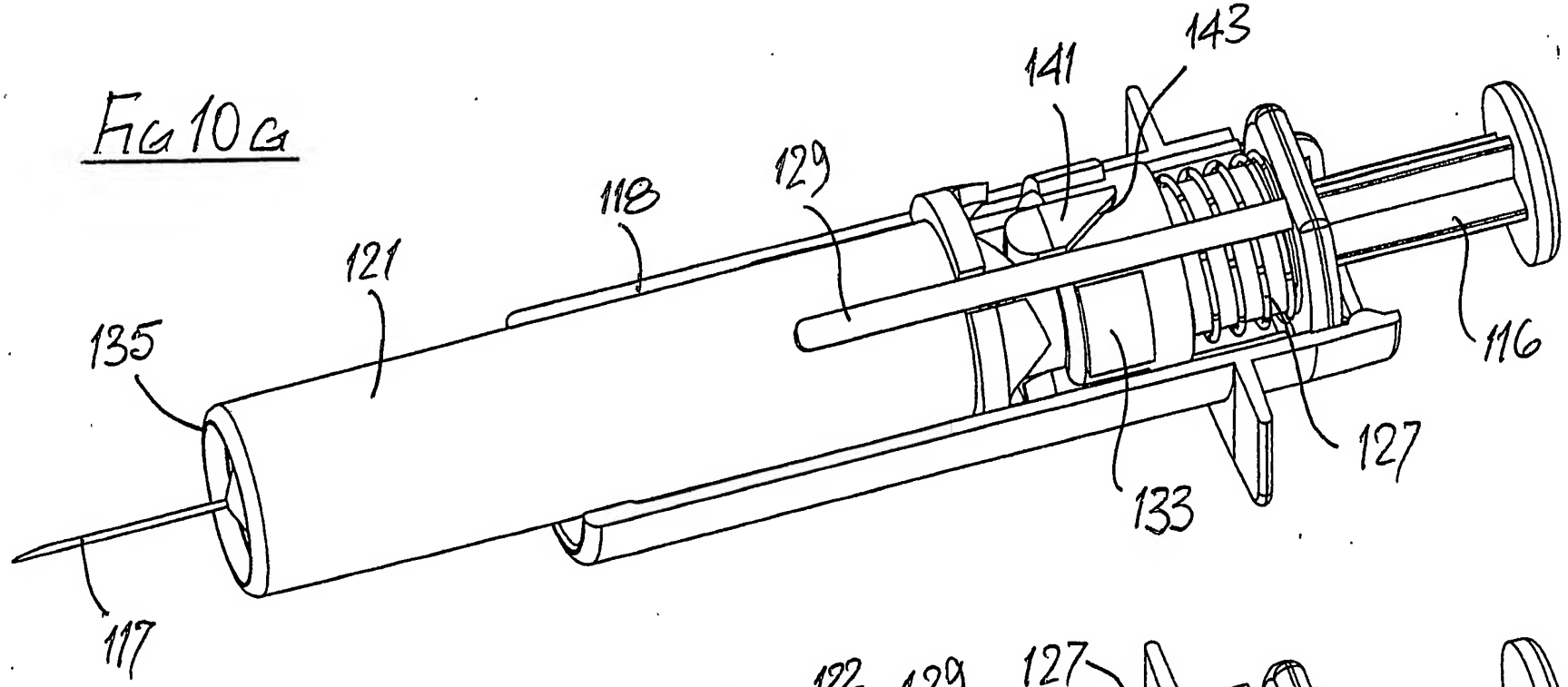


FIG 10 F

FIG 10G



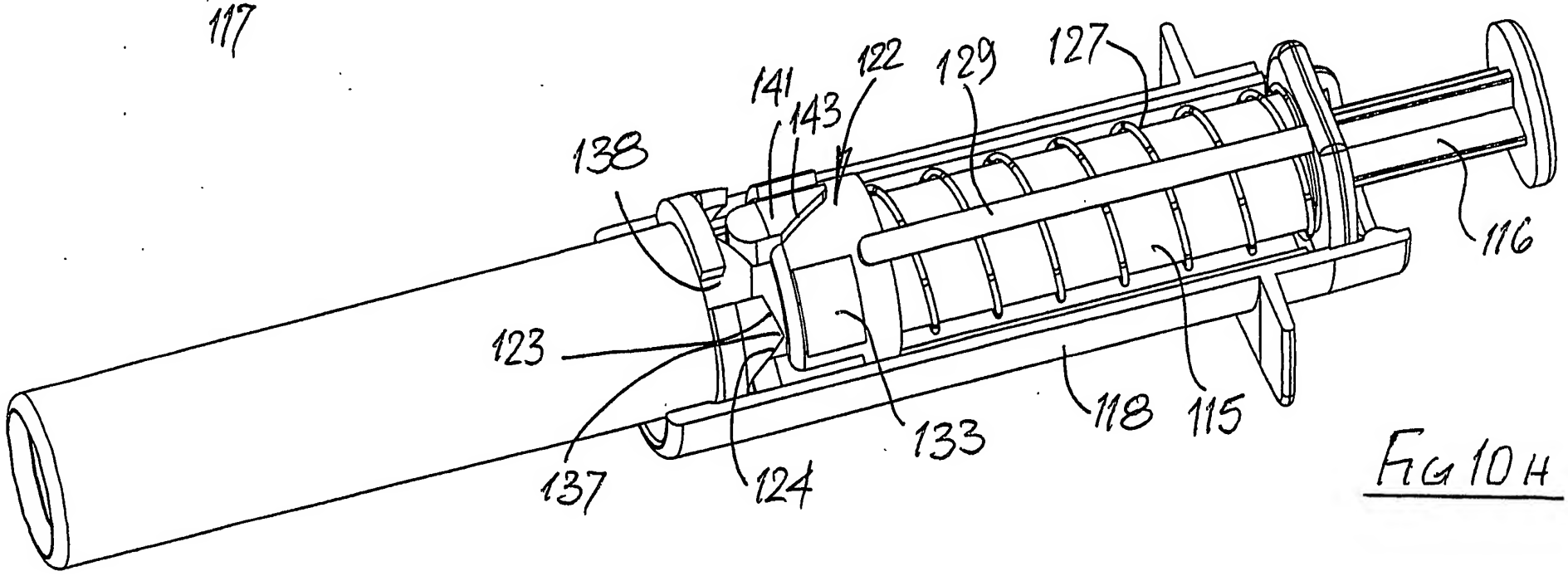


FIG 10H

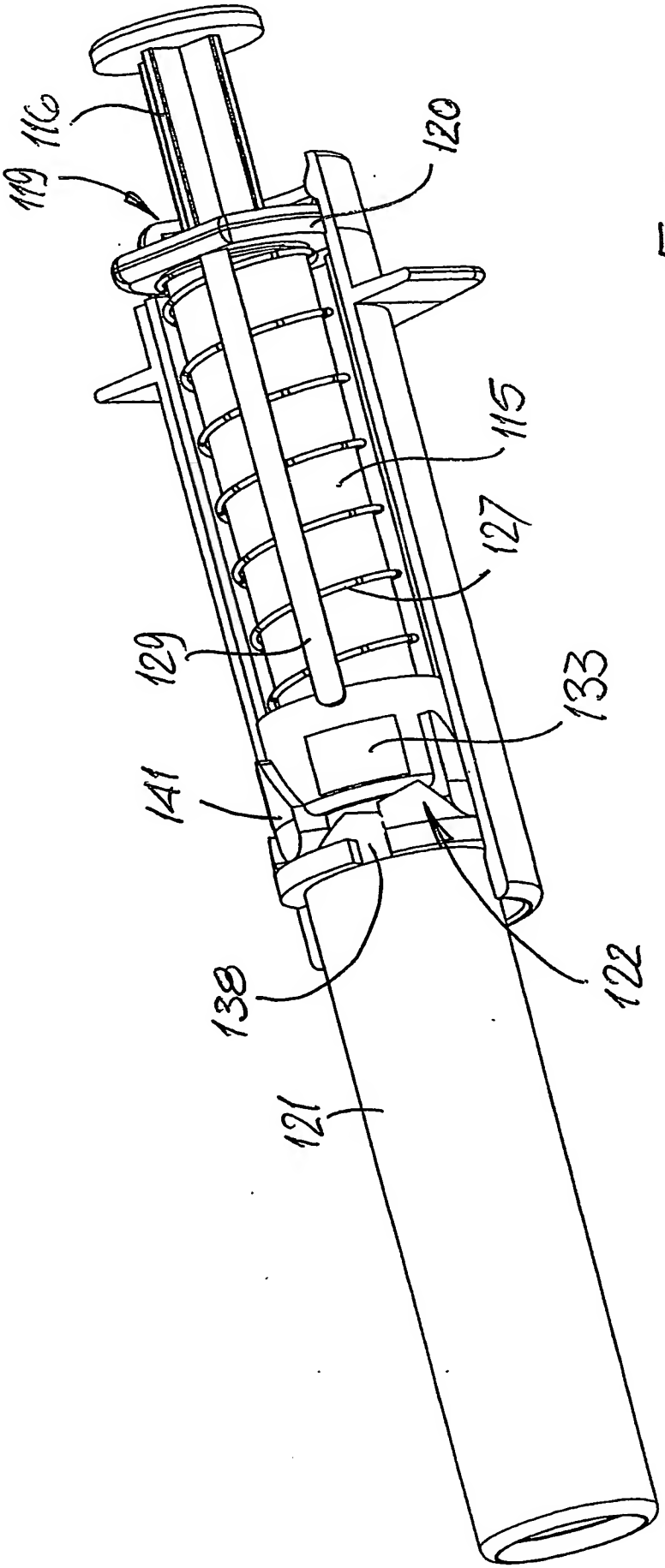


FIG 10 I